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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: **UBER, III** Confirmation Number: 5530
Application No.: **09/939,656** Group Art Unit: 3763
Filed: August 28, 2001 Examiner: Matthew F. DESANTO
Title: **INJECTION APPARATUS INCLUDING REUSABLE AND DISPOSABLE FLUID PATHS FOR DELIVERING FLUID TO MULTIPLE PATIENTS**

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- PRE-APPEAL BRIEF REQUEST FOR REVIEW -

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellant hereby requests that a panel of Examiners formally review the legal and factual basis of the rejection in the above-identified application prior to the filing of an Appeal Brief. Appellant asserts that the outstanding rejection (now on Appeal by virtue of the concurrently filed Notice of Appeal) is clearly improper based upon errors in facts.

I. APPEALED REJECTIONS

Appellant requests review of the following rejections: claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Thompson '166 (U.S. Patent No. 4,710,166) in view of Wortrich '643 (U.S. Patent No. 4,750,643) and Kampfe '847 (U.S. Patent No. 5,450,847); rejected claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Orkin '444 (U.S. Patent No. 4,925,444) in view of Wortrich '643 and Kampfe '847; and rejected claims 13-18, 63-65, 67-78, 80-88, and 90-91, under 35 U.S.C. §103(a), as allegedly being unpatentable over Kerns '706 (U.S. Patent No. 4,756,706) in view of Kampfe '847 and Wortrich '643.

II. ARGUMENTS FOR TRAVERSAL

1. References Fail to Teach the Invention & their Combination Improper.

Appellant traverses the prior art rejections because none the primary references, Thompson '166, Orkin '444, or Kerns '706, whether analyzed individually or in combination with the numerous secondary references, disclose, teach, or suggest the claimed invention.

Moreover, as discussed in detail in the previous responses, the teachings of the applied references are either incompatible, thereby rendering their combination improper, or effectively teach away from the claimed invention.

With respect to the first set of prior art rejections, which combines Thompson '166 with Wortrich '643 and Kampfe '847, Appellant reiterates that the Thompson '166 reference merely teaches a system for the sequential delivery of two fluids to *a single patient* and provides a comprehensive explanation of the importance of reducing entry trauma to *a single patient* when sequentially administering medicaments. (See Thompson '166: col. 1, lines 9-25, col. 3, lines 51 – 52). As such, there is not even a remote suggestion or inference that the Thompson '166 system is capable of providing a *method of delivering fluid to multiple patients*, as required by each of the independent claims. Nor is there anything in Thompson '166 that teaches or suggests the limitations specifically requiring connecting the second end of a first per-patient disposable portion to the reusable portion, connecting the first end of the first per-patient disposable portion to a first patient of multiple patients, selectively delivering fluid from one or both of the first and second fluid sources to the first patient through the first per-patient disposable portion, connecting a second per-patient disposable portion to the reusable portion, connecting a second patient of multiple patients, and selectively delivering fluid from one or both of the first and second fluid sources to the second patient through the second per-patient disposable portion.

Equally notable, the secondary references are incapable of curing the noted deficiencies of Thompson '166. The Kampfe '847 reference is directed to a system and method of preparing and mixing suitable dosage forms of fluid contrast medium for individual examination. (See Kampfe '847: col. 3, lines 10-20). There is nothing in Kampfe '847, however, that remotely suggests *the direct dispensation of fluids to a patient* - much less provide a *method of delivering fluid to multiple patients*, as required by the independent claims. And, like Thompson '166, Kampfe '847 fails to teach or suggest the limitations noted above. The Wortrich '643 reference is directed to a system and method for dispensing fluid 12 from a *single container* 10 to a succession of multiple patients. (See Wortrich '643: col. 3, line 14 – col. 4, line 39; *see also* Abstract; FIG. 1). As such, Wortrich '643 is incapable of teaching a method of delivering fluids to multiple patients that includes a second fluid source, a device adapted to mix fluids from the first and second fluid sources, and selectively delivering fluids, as required by the independent claims.

Regarding the propriety of combining references, Appellant respectfully submits that the first criteria in establishing a *prima facie* case of obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. As a corollary to this requirement, the Federal Circuit has specifically held that the mere fact that *the prior art could be modified* as proposed by the Examiner *is not sufficient* to establish a *prima facie* case of obviousness. (See, *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (*emphasis added*). Rather, the Examiner *must explain why the prior art would have suggested* to one of ordinary skill in the art *the desirability of the modification*. (See *Fritch*, 972 F.2d at 1266, 23 USPQ2d at 1783-84) (*emphasis added*).

With this in mind, Appellant cannot understand how the Thompson '166, Wortrich '643, and Kampfe '847 references could possibly be combined, as not only is there no suggestion in any of the references to combine and/or modify the features to render the claimed invention – the references are directed to configurations that either teach away from the invention or are incompatible with each other. That is, Thompson '166 is only directed to sequential delivery of two fluids to a single patient, Kampfe '847 only teaches the mixing of fluids and has nothing to do with fluid delivery, and Wortrich '643 is directed to dispensing a single fluid to multiple patients. Clearly, the combination of these references can only be based on impermissible hindsight.

With respect to the second set of prior art rejections, which combines Orkin '444, Wortrich '643, and Kampfe '847, Appellant submits that the Orkin '444 reference is directed to a closed, multiple-fluid delivery system that can deliver a plurality of preselected fluids in a preselected sequence via a closed fluid-flow delivery system to an output port *for a single patient*. (See Orkin '444: col. 3, lines 34-38; *see also* Abstract). Thus, like Thompson '166, there is nothing in Orkin '444 that is remotely suggests a *method of delivering fluid to multiple patients* – much less teaching the remaining limitations of the independent claims. And, for reasons already discussed above, the Wortrich '643, and Kampfe '847 references are incapable of curing the deficiencies of Orkin '444 as well as lack any suggestion to combine and/or modify the features to render the claimed invention.

With respect to the third set of prior art rejections, which combines Kerns '706, Wortrich '643, and Kampfe '847, Appellant submits that the Kerns '706 reference is directed to a system that employs a plurality of infusion pump modules for delivering a plurality of fluids to *a single patient*. As such, Kerns '706 clearly fails to suggest a *method of delivering fluid to multiple patients* as well as the remaining limitations required by the independent claims. And, once again, the Wortrich '643, and Kampfe '847 references are incapable of curing the deficiencies of Kerns '706.

2. Duplication of Parts Argument is Misplaced.

The Examiner has maintained that the use of multiple infusion lines is a mere duplication of parts and in the Advisory Action of June 5, 2006 indicated that it would be obvious to reuse a device more than once to treat more than one patient. Such assertions are based on the old, *per se* rule of *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960), which has been distinguished on many grounds. Indeed, in *Ex parte Granneman*, 68 USPQ2d 1219 (Bd. Pat. App. & Int. 2003), the Board of Patent Appeals and Interferences rebuked the use of the *per se Harza* rule by stating that “reliance on *per se* rules of obviousness is legally incorrect and must cease.” (*Granneman*, 68 USPQ2d at 1221)(quoting, *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995)).

Like the *Granneman* case, the Examiner does not explain why, based on the comparison between the facts of *Harza* and the claimed invention, the legal conclusion should be the same as that of *Harza*. Appellant points out that the *per se Harza* rule cannot be haphazardly applied simply because the prior art teaches a configuration for accomplishing a function for a single user while the claimed invention is directed to a configuration that accomplishes a function for multiple users. By now, it should be appreciated that the present invention does not merely claim a collection of multiple individual stand-alone devices to service multiple patients. Rather, the claimed invention provides a specific methodology and configuration for delivering fluids to multiple patients that has not been taught, suggested, or otherwise contemplated by the prior art. The features of the claimed invention, including multiple parts that achieve the invention’s intended purpose must, therefore, be given patentable weight consistent with basic claim construction and obviousness analysis principles.

3. Advisory Action Improper.

The Examiner denied entry of the Amendment of May 12, 2006 and issued the Advisory Action of June 5, 2006 alleging that the claim changes raise new issues that would necessitate a new search. Appellant submits that changing "delivering" to "selectively delivering" does not raise any new issue, as the feature of selectively delivering fluids has been claimed and addressed, via the rotary valve limitation, since the Amendment of January 27, 2004 and currently remains as part of dependent claim 67. Appellant submits that such a feature should have been already been searched many times over and, accordingly, the Amendment of May 12, 2006 should be entered.

III. CONCLUSION

Appellant respectfully submits that, for at least the reasons detailed herein, the Examiner has not met the initial burden of establishing a *prima facie* case of obviousness as the references fail to teach or suggest all the features recited in the rejected claims and the combination of such references is, at the very least, unreasonable. Appellant further submits that the Examiner's arguments regarding duplication of parts and the raising of new issues are misguided and manifestly unfair.

Respectfully submitted,

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